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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,937	06/30/2000	MARIA EUGENIA MEIRINHOS DA CRUZ	249-119P	2705

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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 03/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/529,937	Applicant(s) Da Cruz
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 10, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *23-40* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *23-40* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The request for the extension of time and amendment dated 1-10-02 are acknowledged.

Claims included are 23-40.

Claim Rejections - 35 U.S.C. § 112

1. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

2. **Claims 23-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Dinitro aniline is a specific compound; hence it is unclear as to what applicant intends to convey by 'one Dinitro aniline' in the independent claims. This rejection is maintained since applicant has not addressed this issue.

What is meant by 'antisublimating agent' as recited in claim 25? Furthermore, this claim preamble is the process of preparing plurality of distinct population of liposomes; yet this process claim does not recite how distinct populations are produced.

'the dehydration step' in claim 26 lacks an antecedent basis in claim 25.

'any other sugar solution' is not a positive recitation and hence renders claim 30 indefinite. Similar is the case with claim 36.

'Small' and 'rest' in claim 34 are relative terms and hence render the claims indefinite.

'What is a non-saline solution' as recited in claim 29 and 35?

Does the term, 'derivatives' on line 4 of claim 37 is for cholesterol only or for the other lipids recited before cholesterol. 'Phosphotidylglycerol is (PG) and not (PC) as recited in this claim.

What is being conveyed by 'the Dinitro aniline comprises trifluralin' in claim 38? This compound is a derivative of Dinitro aniline; as pointed out above, Dinitro aniline is a specific compound.

Claim 39 depends from to independent claims which is improper.

3. **Claim 40 provides for the use of the composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.**

Claim 40 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23-24 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/31970 of record.

WO discloses liposomal formulations containing trifluralin; the liposomes are made of phosphatidylcholine. Since the process of preparation in the prior art results in a liposome population of different sizes, the reference meets the requirements of dependent claims (note the abstract and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO relates to a method of production of liposomal microencapsulated product for agricultural formulations. This argument is not found to be persuasive since these are composition claims and intended use has no patentable significance in composition claims. Applicant argues that liposomes prepared according to the present application are so different and are incorporated into the vesicle with

populations of particles specifically designed to reach the diverse intended organs. This argument is not found to be persuasive since according to instant claims the liposomal sizes can be anywhere from above 400 to below 100 and as applicants themselves admit on page 6 of their response that "because of the large numbers of particles in any given population, a Gaussian type distribution prevails", the prior art process results in liposomes having different diameters and therefore, reads on instant claims irrespective of the process by which they are prepared.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

7. Claims 23-24 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's statements of prior art in view of Steck (4,186,183), Rao (4,594,241) individually or in combination or vice versa.

Applicant in the paragraph bridging pages 3 and 4 of the specification indicate that the herbicide, trifluralin is a well-known anti-leishmania drug.

Steck teaches liposomal carriers for the treatment of leishmaniasis (note the abstract). According to Steck the liposomes are taken up rapidly by cells and intra-cellular lysosomes of the reticuloendothelial system and that the characteristics of liposomes

suggested that they might have a potential for application of carriers for anti-leishmania agents. Steck also teaches that the cells and tissues in which the liposomes are readily taken up are the very locations in which the Leishmania organisms predominantly reside (note col. 2, lines 6-26). The anti-leishmania drug taught by Steck however, is not the claimed drug.

Rao similarly teaches the effectiveness of the liposomally encapsulated anti-leishmania drugs against this organism (note the abstract, examples and claims). The anti-leishmania drug taught by Rao however, is not the claimed compound.

The use of the liposomes as carriers of trifluralin would have been obvious to one of ordinary skill in the art because of effectiveness of liposomes as carriers of anti-leishmania drugs taught by Steck and Rao. Alternately, the use of trifluralin in the liposomes of Steck or Rao would have been obvious to one of ordinary skill in the art with the expectation of obtaining the benefits of the liposomes since trifluralin is a art known anti-leishmania drug.

Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that none of the references refer to trifluralin. The examiner agrees, but points out that these reference teach antileishmania drugs and trifluralin is a well-known anti-leishmania drug. With regard to UK reference, applicants argue that Trifluoralin is removed from liposomes, but provide no evidence. Applicants' arguments with regard to sizes have already been addressed by the examiner.

8. Claims 23-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's statements of prior art in view of Steck (4,186,183), Rao (4,594,241) individually or in combination or vice versa as set forth above, further in view of GB 2 002 319: or WO 95/31970 cited above, further in view of GB 2 002 319.

Neither Steck nor Rao nor WO teach the dehydration of the liposomes and hydrating again.

GB teaches that liposomes can be dehydrated for storage as a stable powder. According to GB such dehydrated powders can be stored for long periods and from which a dispersion of liposomes can be reconstituted (note the abstract).

Dehydrating the liposomes of Steck or Rao or WO would have been obvious to one of ordinary skill in the art because GB teaches that the liposomal powders can be stored for a long time.

Applicants provide no specific arguments for this rejection and hence the rejection is maintained.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a

properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 27, 2002